

II. REMARKS

A. Status of the Claims

Claims 6-7, 13-16 and 24-30 are pending. Claims 1-5, 9-12, 17-23 were previously cancelled. Claims 6 and 24 have been amended without prejudice. Support for these amendments can be found in the original specification as filed, e.g., page 9, line 25; page 10, lines 1-4 and page 16, line 21 to page 18, line 24. Applicants respectfully submit that no new matter has been added by virtue of this amendment.

B. Claim rejection under 35 U.S.C. §103

1. Goldie et al.

In the Office Action, the Examiner rejected claims 6-8, 13-16 and 24-30 under 35 U.S.C. §103(a) over Goldie et al. (U.S. 4,844,909).

Prior to addressing the present rejection, Applicants respectfully point out that independent claims 6 and 24 have been amended herein without prejudice to recite, in part, “a method for treating pain...comprising administering...a solid, controlled-release oral dosage form comprising 8 to 64 mg of hydromorphone or a pharmaceutically acceptable salt thereof, incorporated into a controlled-release formulation comprising a tablet overcoated with a cured stabilized coating derived from an aqueous dispersion of a hydrophobic polymer ...” (emphasis added).

With respect to the rejection under 35 U.S.C. § 103(a), Applicants respectfully submit that the Goldie reference fails to teach or suggest a hydromorphone formulation comprising a tablet overcoated with a cured stabilized coating derived from an aqueous dispersion of a hydrophobic polymer as recited in the present claims. Therefore, Applicants submit that the Goldie reference cannot teach or suggest the presently claimed method which utilizes such a formulation.

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In support of this position, Applicants note that not only does the Goldie reference fail to teach a coating derived from an aqueous dispersion of a hydrophobic polymer, the reference further fails to recognize the art recognized problem that dissolution release profiles change on ageing. See page 16, lines 26 -27 of the present specification. Therefore, the Goldie reference does not suggest a solution to this problem, i.e., subjecting the aqueous dispersion of hydrophobic polymer to a curing step in order to provide a stabilized release rate.

Accordingly, Applicants respectfully submit that the Goldie reference fails to teach or suggest the presently claimed method utilizing a hydromorphone controlled-release formulation comprising a tablet overcoated with a cured stabilized coating derived from an aqueous dispersion of a hydrophobic polymer as recited in the present claims and request removal of the rejection under 35 U.S.C. §103(a).


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III. CONCLUSION

In view of the amendments made and arguments presented, it is respectfully requested that the Examiner's rejections be withdrawn. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,
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